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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

Date: 2/11/2020

Subject: Efficacy Review for Puffs, EPA Reg. No. 1677-250  
(DP Barcode: 455043, E-Submission: 43657)

From: Samantha Collins  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)

A handwritten signature in blue ink, appearing to read "Samantha Collins", is positioned to the right of the "From:" field.

Thru: Cesar E. Cordero, Acting Team Lead  
Efficacy Evaluation Team  
Product Science Branch  
Antimicrobials Division (7510P)  
Date Signed: January 5, 2020

A handwritten signature in blue ink, appearing to read "Cesar E. Cordero", is positioned to the right of the "Thru:" field.

To: Aline Heffernan/Kathryn Montague  
Regulatory Management Branch I  
Antimicrobials Division (7510P)

Applicant: ECOLAB, INC.  
1 Ecolab Place  
St. Paul, MN 55102

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Hydrogen Peroxide .....	10.70%
Peroxyoctanoic Acid.....	0.63%
Peroxyacetic Acid.....	2.38%
<u>Other Ingredients</u> .....	86.29%
<u>Total</u> .....	100.0%

## **I BACKGROUND**

**Product Description (as packaged, as applied):** Liquid concentrate

**Submission type:** Label amendment

**Currently registered efficacy claim(s):** Hard, non-porous surface dilutable liquid disinfectant (bactericidal, virucidal, fungicidal), food contact sanitizer, and non-food contact sanitizer.

**Requested action(s):** Add biofilm sanitization claims and Emerging Viral Pathogen claim.

**Documents considered in this review:**

- Letter from applicant to EPA dated October 16, 2019
- Data Matrix (EPA Form 8570-35)
- 3 new efficacy studies (MRIDs 50968201-50968203)
- 1 cited efficacy study Emerging Viral Pathogen claim (MRID 49467412)
- Proposed label dated 10/16/19
- Confidential Statement of Formula (EPA Form 8670-4) dated 9/14/2018.
- Terms of Registration Letter (included in cover letter) dated October 16, 2019
- Protocol Review dated 5/10/2019 (Reg. # 1677PA29, DP# 450647, E-submission # 35317)

## II PROPOSED DIRECTIONS FOR USE

### “Sanitizing Biofilm

Synergex acid sanitizer is recommended for use on pre-cleaned, hard, non-porous surfaces in food and beverage processing, industrial, and institutional applications.

When applied to pre-cleaned hard, non-porous food contact and other pre-cleaned, hard, non-porous surfaces conducive to biofilm formation, Synergex is effective as a biofilm sanitizer against *Listeria monocytogenes* (ATCC 49594) and *Pseudomonas aeruginosa* (ATCC 15442). Use a cleaning solution suitable to remove gross particles, followed by a potable water rinse as required by the governing sanitary code. Sanitize according to the table below using immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces must be exposed to the sanitizing solution for the required contact time unless a longer time is specified by the governing sanitary code. Drain thoroughly. See table for rinsing requirements.

### Biofilm

#### Sanitizing Treatment

Use Rate	Minimum Conditions for Use	Post-Treatment Rinse Requirement
1 fl. oz. / 4–4.5 gallons of [water] [tap water] [up to 500 ppm hard water] (0.173–0.195%, 1730–1950 ppm product)	10 minutes (at a minimum of 33°C)	No rinse necessary
1 fl. oz. / 4–4.5 gallons of [water] [tap water] [up to 500 ppm hard water] (0.173–0.195%, 1730–1950 ppm product)	25 minutes	No rinse necessary
1.54–1.92 fl. oz. / 3 gallons of [water] [tap water] [up to 500 ppm hard water] (0.40–0.50%, 4000–5000 ppm product)”	5 minutes	Potable water rinse required

### III STUDY SUMMARIES

1.	MRID	50968201	Study Completion Date:	10/15/2019			
Study Objective		Biofilm food contact Sanitization					
Testing Lab; Lab Study ID		Ecolab, 1900079					
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> ATCC 15442 and <i>Listeria monocytogenes</i> ATCC 49594					
Test Method		Food Contact Surface Associated Biofilm Test					
Application Method		Dilutable Liquid					
Test Substance Preparation	Name/ID	Synergex					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	NB14981-47, NB14981-48, NB14981-49					
	Preparation	Tested concentration: LCL Dilution: 1oz/ 4.6 gallons (≈1:590) Diluent: 500 ppm synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		304 stainless steel, 5 per batch					
Test conditions		Contact time	25 min	Temp	21°C	RH	N/A
Neutralizer		D/E Broth					
Reviewer comments (i.e. protocol deviations etc.)							

2.	MRID	50968202	Study Completion Date:	10/15/2019			
Study Objective		Biofilm food contact Sanitization					
Testing Lab; Lab Study ID		Ecolab, 1900080					
Test organism(s) <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> ATCC 15442 and <i>Listeria monocytogenes</i> ATCC 49594					
Test Method		Food Contact Surface Associated Biofilm Test					
Application Method		Dilutable Liquid					
Test Substance Preparation	Name/ID	Synergex					
	Lots <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	NB14981-47, NB14981-48, NB14981-49					
	Preparation	Tested concentration: LCL Dilution: 1.54oz/ 3 gallons (≈1:250) Diluent: 500 ppm synthetic hard water					
Soil load		N/A					
Carrier type, # per lot		304 stainless steel, 5 per batch					
Test conditions		Contact time	5 min	Temp	21°C	RH	N/A
Neutralizer		D/E Broth					
Reviewer comments (i.e. protocol deviations, etc.)							

<b>3.</b>	<b>MRID</b>	50968203	<b>Study Completion Date:</b>		10/15/2019		
<b>Study Objective</b>		Biofilm food contact Sanitization					
<b>Testing Lab; Lab Study ID</b>		Ecolab, 1900085					
<b>Test organism(s)</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Pseudomonas aeruginosa</i> ATCC 15442 and <i>Listeria monocytogenes</i> ATCC 49594					
<b>Test Method</b>		Food Contact Surface Associated Biofilm Test					
<b>Application Method</b>		Dilutable Liquid					
<b>Test Substance Preparation</b>	<b>Name/ID</b>	Synergex					
	<b>Lots</b> <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 3	NB14981-47, NB14981-48, NB14981-49					
	<b>Preparation</b>	Tested concentration: LCL Dilution: 1oz/ 4.6 gallons (≈1:590) Diluent: 500 ppm synthetic hard water					
<b>Soil load</b>		N/A					
<b>Carrier type, # per lot</b>		304 stainless steel, 5 per batch					
<b>Test conditions</b>		<b>Contact time</b>	10 min	<b>Temp</b>	21°C	<b>RH</b>	N/A
<b>Neutralizer</b>		D/E Broth					
<b>Reviewer comments</b> (i.e. protocol deviations, etc.)							

#### IV STUDY RESULTS

##### Biofilm Food-Contact Sanitization

MRID	Organism	Log Reduction			Mean Log Density
		Batch NB14981-47	Batch NB14981-48	Batch NB14981-49	Test dates (9/12/19) (9/19/19) (9/26/19)
25-minute contact time, 500 ppm hard water, 1oz/ 4.6 gallons					
50968201	Pseudomonas aeruginosa (ATCC 15442)	>6.91	>6.74	>6.19	9.16
					9.00
					9.25
	Listeria monocytogenes (ATCC 49594)	>6.43	>6.47	>6.33	6.99
					7.03
					6.89
5-minute contact time, 500 ppm hard water, 1.54oz/ 3 gallons					
50968202	Pseudomonas aeruginosa (ATCC 15442)	>8.51	>8.20	>8.41	9.07
					9.04
					9.07
	Listeria monocytogenes (ATCC 49594)	>6.57	>6.47	>6.40	7.13
					7.03
					6.96
10-minute contact time, 500 ppm hard water, 1oz/ 4.6 gallons					
50968203	Pseudomonas aeruginosa (ATCC 15442)	>8.55	>8.52	>8.27	9.08
					9.01
					9.11
	Listeria monocytogenes (ATCC 49594)	>6.40	>6.18	>6.30	6.74
					6.86
					6.96

## V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50968201	Biofilm Food-contact Sanitization	Hard, non-porous surfaces	Use-Dilution (1oz/ 4.6 gallons)	25 minutes	N/A	500 ppm hard water	<ul style="list-style-type: none"> <li>• <i>Pseudomonas aeruginosa</i> (ATCC 15442)</li> <li>• <i>Listeria monocytogenes</i> (ATCC 49594)</li> </ul>	Yes
50968202			Use-Dilution (1.5oz/ 3 gallons)	5 minutes				
50968203			Use-Dilution (1oz/ 4.6 gallons)	10 minutes				
49467412	Emerging Pathogen:  -Enveloped Viruses	Hard, non-porous surfaces	Use-Dilution (1 oz/ 7 gallons)	5 minutes	5%	500 ppm hard water	<ul style="list-style-type: none"> <li>• Reovirus type 3 (ATCC VR-232, Strain Abney)</li> </ul>	Yes

## VI LABEL COMMENTS

1677-250/ Label date: 10/16/19

1. The proposed label claims that the product, Synergex, a use-dilution liquid concentrate (1oz/ 4.5 gallons), is an effective biofilm sanitizer against the following on hard, non-porous surfaces in the presence of no organic soil for a 25-minute and 10-minute contact time:

*Pseudomonas aeruginosa* (ATCC 15442)

*Listeria monocytogenes* (ATCC 49594)

These claims are **acceptable** as they are supported by the submitted data.

2. The proposed label claims that the product, Synergex, a use-dilution liquid concentrate (1.54-1.92 oz/ 3 gallons), is an effective biofilm sanitizer against the following on hard, non-porous surfaces in the presence of no organic soil for a 5-minute contact time:

*Pseudomonas aeruginosa* (ATCC 15442)

*Listeria monocytogenes* (ATCC 49594)

These claims are **acceptable** as they are supported by the submitted data.

3. The proposed label claims that the product, Synergex, qualifies for the following emerging viral pathogens claims as described in the letter from the applicant to EPA dated: October 16, 2019

<i>For an emerging viral pathogen that is a/an...</i>	<i>...follow the directions for use for the following organisms on the label:</i>
Enveloped virus	Reovirus type 3 (ATCC VR-232, Strain Abney)
Large Non-Enveloped virus	n/a
Small Non-Enveloped virus	n/a

These claims are **acceptable** as they are supported by the cited data. This product meets the criteria to make claims against certain emerging viral pathogens from the following viral category[ies]:

-Enveloped Viruses



4. Make the following changes to the proposed label:

- a. On page 1, qualify “virucide” either in text or with an asterisk to indicate the viruses tested
- b. On pages 2 and 6 of the proposed label: replace the words “heavily” with “visible” when used as a descriptor of “soiled areas/surfaces”. A 5% soil load is representative of visibly clean surfaces.
- c. On page 5 of the proposed label: revise the claim “To prevent the spreading/cross contamination of harmful organisms from area to area” to include “on treated surfaces” (i.e. “To prevent the spreading/cross contamination on treated surfaces of harmful organisms from area to area”)
- d. On page 5 of the proposed label, for the contact time of 25 minutes, application by immersion only should be specified. For application via spray or circulation, this extended contact time is not acceptable.
- e. On page 6 of the proposed label: revise claim “prevent tracking harmful organisms into animal areas” to include “from treated surfaces” (i.e. “prevent tracking harmful organisms from treated surfaces into animal areas”.
- f. On page 6 of the proposed label: Qualify the claim “Synergex disinfects as it cleans in one operation” with disinfection use directions. For example, “when used according to disinfection instructions/directions” or direct the user to follow the directions in the “Combination Disinfection and Cleaning” section of the label.
- g. On page 10 of the proposed label: remove the word “heavy” as the qualifier of organic load as seen in: “Formulated for rapid soil penetration and ability to stand up to heavy organic loads.” The qualifier may imply increased efficiency.
- h. On pages 11 and 12 of the proposed label, remove “remove” or “removing” and “break down” from the following claims:
  - a. “[Proven] [Developed] [Approved] [Formulated] to [kill] [reduce] [remove] [break down] [penetrate] [destroy] biofilms at sanitizer concentration.”
  - b. “[Penetrates] [and] [kills] [and] [removes] biofilms from hard, non-porous food contact surfaces.”
  - c. “Synergex [, when used as a no-rinse sanitizer,] can [penetrate] [and] [remove] biofilms”
  - d. “Remove biofilms while you sanitize”
  - e. “[Remove] [reduce] [kill] [sanitizes] biofilms [on food contact surfaces] with Synergex.”
  - f. “[Remove] [reduce] [kill] [sanitizes] biofilms [on food contact surfaces] with Synergex.”
  - g. “[Remove] [reduce] [kill] [sanitizes] biofilms [on food contact surfaces] with Synergex.”
- i. On page 11 and 12 of the proposed label remove the claim “Reduces food safety risks”, “improves your food safety program”, and “reduces food recall risk” as these claims may be false or misleading to the user.
- j. On page 12 of the proposed label, remove the claim “Synergex is effective at eliminating *Pseudomonas aeruginosa* and *Listeria monocytogenes* containing biofilms at [no rinse] sanitizer levels”.
- k. On page 12 of the proposed label delete: “[prevent] the buildup” as seen on the following statement: “Ideal for central sanitize [CIP] systems to [kill] [reduce] [prevent] the buildup of biofilms”. This may be interpreted as continuous/extended disinfection activity.